Food and Drug Administration
Department of Health and Human Services

FY 2004 PERFORMANCE REPORT TO THE CONGRESS

for the

Medical Device User Fee and Modernization Act

Center for Biologics Evaluation and Research

Center for Devices and Radiological Health

Commissioner's Report

I am pleased to report that the Food and Drug Administration (FDA) is making good progress in implementing the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and that the Agency's overall performance to date is consistent with the comprehensive and challenging performance goals that are a key feature of MDUFMA.

MDUFMA requires close collaboration with stakeholders and increased communication with applicants. FDA is working to clarify its regulatory requirements and make its decisions more transparent through new guidance and educational materials. We continue to make every effort to reduce the costs as well as the burden associated with product review. These efforts should help applicants improve the quality of their submissions, and will help FDA provide more rapid, better-focused reviews. Our ultimate objective is to make important new medical devices available to patients and health care providers earlier, while continuing to ensure the quality, safety, and effectiveness of those devices.

FDA's efforts in fiscal year (FY) 2003 and FY 2004 provide a solid foundation to build on during FY 2005 and in future years.

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

Executive Summary

On October 26, 2002, MDUFMA was signed into law. MDUFMA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to collect user fees from manufacturers who submit certain applications to market medical devices. In exchange for this authority, MDUFMA requires that the FDA pursue a comprehensive set of review performance goals and commitments to improve the timeliness and predictability of medical device reviews.

FDA has made good progress in implementing MDUFMA and is making satisfactory progress towards achieving the performance goals set under MDUFMA. FDA has worked hard to communicate the new requirements and challenges of MDUFMA to its stakeholders. The Agency has worked with its stakeholders to ensure that the implementation of the new law proceeds smoothly. FDA is confident that the implementation of MDUFMA will result in significant benefits to industry, health care professionals, and, most importantly, patients.

FY 2004 Activities

FDA continued to focus on consulting with its stakeholders, developing guidance documents, and designing and building the new review processes and process improvements required to meet MDUFMA's challenging performance goals. As with FY 2003, only two quantifiable performance goals were in effect during FY 2004. Among the key achievements during FY 2004 were:

- **Guidance and Procedural Development.** FDA issued 11 MDUFMA guidance documents during FY 2004: two draft guidance documents, seven final guidance documents, and two revised editions of final guidance documents issued during FY 2003.
- **Stakeholder Communication and Consultation.** FDA expanded its outreach to stakeholders, providing additional information through the MDUFMA Internet site (www.fda.gov/cdrh/mdufma), through presentations at industry and professional meetings, and at quarterly meetings with stakeholders. In December 2003, FDA held its first Annual Stakeholder Meeting to report on the implementation of MDUFMA and to hear directly from stakeholders.
- **Public Notification.** FDA published 27 Federal Register notices to provide essential information to stakeholders on new guidance documents, proposed rules, regulatory actions, user fees, and other topics, and to also request comments and suggestions from stakeholders.
- **Congressional Reporting.** FDA submitted its first MDUFMA performance report and first MDUFMA financial report to Congress covering FY 2003. FDA's new Office of Combination Products submitted its first annual report to Congress, which included information on MDUFMA-related products.

- **Hiring and Training of Staff.** The Center for Devices and Radiological Health (CDRH) applied 735 full-time equivalents (FTEs) to the process of reviewing device applications during FY 2004, an increase of 60 FTEs since FY 2002. The Center for Biologics Evaluation and Research (CBER) applied 67 FTEs, an increase of 9 FTEs. FDA's hiring focused on priorities identified by product review groups. In addition, FDA expanded its use of outside experts.

FY 2003 and FY 2004 Performance Goals

MDUFMA's review performance goals were developed in recognition of the fact that FDA needs a 2-year start-up period (FY 2003 through FY 2004) to hire and train new staff and construct review program infrastructures before substantial progress in improving overall review performance is possible. Consequently, most review performance goals do not go into effect until FY 2005. As of September 30, 2004, three submissions have been subject to specific MDUFMA performance goals and all were associated with FY 2003 submissions. FDA met the review time goal in two of the three submissions acted on in FY 2004. No FY 2004 amendments were received as of September 30, 2004.

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Introduction

> ***. . . prompt approval and clearance of safe and effective devices is critical to the improvement of the public health so that patients may enjoy the benefits of devices to diagnose, treat, and prevent disease . . .***
>
> — Section 101(1) of the Medical Device User Fee and Modernization Act of 2002.

On October 26, 2002, MDUFMA was signed into law. MDUFMA amends the FD&C Act to authorize FDA to collect fees from companies who submit certain applications for marketing of medical devices. In return, MDUFMA requires FDA to pursue a comprehensive set of device review performance goals that will significantly improve the timeliness and predictability of FDA's review of new devices.[1] These performance goals were developed collaboratively and are defined in the Department of Health and Human Services (DHHS) Secretary Thompson's November 14, 2002, letter to Congress.[2] Information about MDUFMA, including the text of the amendments and the performance goals and procedures, can be found at http://www.fda.gov/oc/mdufma.

MDUFMA requires the Secretary to submit two annual reports to Congress for each fiscal year fees are collected: 1) a performance report due within 60 days of the end of the fiscal year, and 2) a financial report due within 120 days of the end of the fiscal year. This document fulfills the first of these requirements for FY 2004. FDA's authority to collect user fees under MDUFMA expires after 5 years.

On April 1, 2004, MDUFMA was amended and expanded by the Medical Device Technical Corrections Act (MDTCA), P.L. 108-214. MDTCA amends MDUFMA to clarify Congress's intent and to improve and expand upon some features of MDUFMA. These changes did not affect the performance goals FDA is pursuing under MDUFMA.

[1] Section 738(g) of FD&C Act, as amended by MDUFMA. Except where noted, all statutory citations in this report are to the FD&C Act, as amended by MDUFMA.

[2] DHHS Secretary Thompson submitted the required letter to Congress on November 14, 2002 (Congressional Record, November 19, 2002, p. S11549). For convenience, this report refers to this letter as "FDA's Commitment Letter." The complete text of the letter is provided in Appendix A.

Overview of MDUFMA

Background

MDUFMA was signed into law on October 26, 2002, amending the FD&C Act to provide FDA important new responsibilities, resources, and challenges. The goal of MDUFMA is to better serve the public health by providing additional funds to FDA for "the process for the review of devices and the assurance of device safety and effectiveness so that statutorily mandated deadlines may be met." The user fees provided by MDUFMA, and the additional appropriations that go with the new law, will provide the following significant benefits:

- Safe and effective medical devices will reach patients more rapidly.
- Manufacturers will receive timely, high quality reviews with greater consistency.
- Resources will be provided to ensure that devices marketed in the United States continue to meet high standards for safety and effectiveness.

The majority of devices associated with MDUFMA are reviewed by CDRH. However, a number of devices that are critical to ensuring the safety, purity, and potency of biologic products, including assuring the safety of our nation's supply of blood and human tissue products, are reviewed by CBER. Additionally, CBER regulates diagnostic tests for retroviruses, including HIV, as well as devices used in cell and gene therapies. An Intercenter Agreement between CBER and CDRH discusses the types of devices regulated by CBER.

MDUFMA Commitments: Goals and Approaches

This report is concerned primarily with the performance goals that are an integral part of MDUFMA. FDA has prepared a summary of MDUFMA, including information on topics not covered by this report; see www.fda.gov/cdrh/mdufma/mdufmasummary.pdf. FDA also prepares an annual financial report that provides information on review fee revenues and expenses and compliance with MDUFMA requirements concerning the collection and use of those fees; the current and past reports are available at www.fda.gov/cdrh/mdufma/reports.

The MDUFMA has three particularly significant provisions related to FDA performance:

- User fees for premarket reviews, including Premarket Applications (PMAs), Product Development Protocols (PDPs), Biologics Licensing Applications (BLAs), certain supplements, and 510(k)s (premarket notification submissions). The revenues from these fees, and from additional appropriations for infrastructure, will allow FDA to pursue a set of performance goals that will provide patients earlier access to safe and effective technology, and will provide more interactive and rapid review to the medical device industry. A small business (sales and receipts of $30 million or less) may pay a reduced fee. The

payment of a premarket review fee is not related to FDA's final decision on a submission.

- Establishment inspections may be conducted by accredited persons (third parties), under carefully prescribed conditions.
- New regulatory requirements for reprocessed single-use devices, including provisions requiring the submission of additional data on devices now being reprocessed, and a new category of premarket submission, the premarket report.

MDUFMA makes several other significant changes, including:

- The existing third-party 510(k) review program is continued through FY 2006.
- The review of combination products (products that combine elements of devices, drugs, or biologics) will be coordinated by a new office (the Office of Combination Products) in the Office of the Commissioner.
- FDA may require electronic registration of device establishments, when feasible.
- Manufacturers may provide electronic labeling for prescription devices used in health care facilities or by a health care professional.
- The sunset provision, which addresses how FDA is to determine the intended use of a device, is revoked.[3] The effect is to make the requirement permanent.
- The law now explicitly provides for modular review of PMAs.

Phased-In Performance Goals

Performance goals increase in number, complexity, and difficulty beginning in FY 2005. Few objectively-measurable goals were applied during FY 2003 and FY 2004, allowing FDA time to hire staff, build infrastructure, provide guidance to industry, and take other actions to implement the new law. More goals go into effect each year from FY 2005 through FY 2007, and the goals become more demanding each year. For example, PMA "first action" goals can be met for the FY 2005 cohort if *75 percent* of the actions occur within the specified review time standard, but these goals require *80 percent* of actions to meet the standard for FY 2006, and *90 percent* for FY 2007. FDA must continually improve its processes and performance if it is to meet these objectives.

[3] Applicable to section 513(i)(1)(E).

MDUFMA's Performance Goals Are Phased In Through FY 2007					
Goal Type	FY 03	FY 04	FY 05	FY 06	FY 07
Measurable Goals Section I, Paragraphs A through H of the FDA Commitment Letter	2	2	20	26	27
Additional Commitments Section I, Paragraphs I through P of the FDA Commitment Letter	8	8	8	8	8
Total Goals and Commitments	10	10	28	34	35

Appendix C provides a table that summarizes all of MDUFMA's objectively-measurable performance goals in effect during each year through FY 2007.

MDUFMA Implementation

In addition to authorizing the FDA to collect user fees for medical device applications, MDUFMA established review performance goals for the Agency. These goals aim to improve review times for medical device applications by up to 25 percent in five years (even more improvement is expected for breakthrough devices). FDA's medical device program resources have been reduced in recent years, and there have been indications that review performance had begun to decline. MDUFMA's review performance goals recognize that FDA will need a two-year start-up period (FY 2003 through FY 2004) to hire and train new staff and rebuild review program infrastructures before it will be possible to make substantial progress in improving overall review performance. Consequently, most review performance goals do not go into effect until FY 2005. User fees, coupled with additional appropriations from Congress, will help the FDA more efficiently and more quickly make safe and effective medical devices available to the public.

FY 2004 Activities and Accomplishments

FDA continued to make steady progress in implementing MDUFMA in FY 2004 and is laying a sound foundation to enable it to vigorously pursue the ambitious performance goals defined under MDUFMA. However, there was no opportunity for FDA to apply either of the two review performance goals for FY 2004 (both related to FDA action on an amendment containing a complete response to an "approvable" letter).[4] As a part of FDA's ongoing commitment to MDUFMA, the Agency is preparing, through guidance and procedural development, management initiatives, and outreach/education activities, to meet the more ambitious performance goals of FY 2005 through FY 2007. Highlights of the activities and accomplishments important to MDUFMA implementation are presented below.

- **Guidance and Procedural Development.** During FY 2004, FDA developed and published 11 guidance documents to explain FDA's requirements under MDUFMA and help applicants improve the quality of their applications.
- **Communications and Consultation with Stakeholders.** FDA expanded its outreach to stakeholders, providing additional information through the MDUFMA Internet site (www.fda.gov/cdrh/mdufma), FDA presentations at industry and professional meetings, and quarterly meetings with stakeholders.

[4] FDA could not apply these goals because the specified conditions for these two goals did not occur before FY 2004 ended. That is, there was no instance where: 1) an applicant submitted an application during FY 2004; 2) FDA issued an "approvable" letter for that application; 3) the applicant submitted an amendment containing a complete response to FDA's "approvable" letter; 4) 30 days passed for FDA to take action on the amendment; and 5) the 30-day period for FDA action closed before the end of FY 2004. FDA often makes a decision on a PMA without issuing an "approvable" letter.

- **First Annual Stakeholder Meeting.** FDA convened the first Annual MDUFMA Stakeholder Meeting on December 3, 2003, to report on the implementation of MDUFMA and to hear directly from stakeholders. The meeting included panel discussions of the user fee process, MDUFMA performance goals, bundling, modular PMA reviews, and other topics. FDA is using this information to refine the implementation of MDUFMA.
- **Reports to Congress.** FDA submitted the following first annual reports to Congress to keep them informed of the Agency's progress in implementing MDUFMA and to fulfill its obligations under the law.
  - FY 2003 MDUFMA Performance Report.
  - FY 2003 Financial Report on MDUFMA user fee receipts and expenditures.
  - Operations Report from FDA's Office of Combination Products.

Implementation Plans for FY 2005

During FY 2005, FDA will expand its efforts, through employee hiring, training, guidance development, electronic tracking/review system expansion, and outreach, to improve the timeliness and efficiency of device review programs and build FDA's capacity to meet the more challenging goals set for later years. Among the key MDUFMA activities scheduled for FY 2005 are:

- Eighteen more performance goals go into effect for FY 2005. As a result, more submissions will be subject to measurable performance goals, and FDA will have to sustain and improve its performance in order to achieve the higher level of performance expected for FY 2005.
- The modular review program, currently restricted to premarket applications, will be extended to panel-track PMA supplements, and FDA will work with stakeholders to develop performance goals for modular reviews.
- FDA will issue guidance explaining how pre-approval inspections may be completed in considerably less time.
- FDA will provide more substantive guidance on how third-party inspections are to be conducted. Additional guidance documents will be prepared; information on these and other efforts will be available on FDA's MDUFMA Internet site, www.fda.gov/cdrh/mdufma.

Report on FY 2004 MDUFMA Performance

This report presents the Agency's performance on MDUFMA performance goals and commitments in FY 2004. Additionally, performance information originally presented in FDA's FY 2003 MDUFMA Performance Report has been updated to include additional actions the Agency has taken since its last report. Unless otherwise noted, all performance data in this section are as of September 30, 2004.

Performance Goals. MDUFMA requires that FDA meet specific performance goals. For each type of submission for which a medical device user fee is assessed, MDUFMA contains two types of performance goals:

- **Cycle Goals**. A cycle goal is a goal on a specified action that precedes a final action on the submission.

  For example, "First action major deficiency letters will issue within 120 days." A major deficiency letter is not a final action; the applicant can continue the review by preparing and submitting an amendment that addresses the deficiencies identified in FDA's letter.

- **Decision Goals**. A decision goal, on the other hand, is a goal on a final action, ending the review process.

  For example, "90 percent of submissions received in FY 2007 will have an FDA decision in 300 days."

Submissions received since the start of FY 2003 (October 1, 2002) are subject to MDUFMA's performance goals. FDA will report annually on the current fiscal year and will update performance from the previous fiscal year. Most of these goals do not begin until FY 2005 or FY 2006 to allow the Agency time to hire and train new staff and construct review program infrastructures.

Performance Commitments. In addition to the performance goals, MDUFMA holds FDA to several commitments related to the medical device review process. These include, for example, programs and activities related to the application of user fee revenues, guidance development for the modular PMA review program,[5] and examination of FDA's bundling policy.[6]

Measuring Performance.[7] Progress on MDUFMA's performance goals and commitments is measured in different ways, based on the type of goal or commitment. The following types of measures are used to capture FDA's progress on meeting MDUFMA's performance goals and commitments:

- **Quantitative Measures**. MDUFMA's performance goals (cycle and decision goals) are quantifiable; that is, progress can be measured and described primarily

[5] See Appendix A, section I, paragraph L.
[6] See Appendix A, section I, paragraph N.
[7] See Appendix B for a more detailed description of performance measures.

through standard statistics (for example, number of submissions, mean review time, median review time, and percent meeting a review time standard).

- **Descriptive Measures**. Alternatively, some MDUFMA commitments are more descriptive in nature. For these, progress is reported through narrative accounts outlining specific actions taken, in addition to any results attributed to those actions.

Receipt Cohort. All FDA review performance statistics are based on a receipt cohort. This methodology calculates performance statistics for submissions for the year they were received, regardless of when FDA ultimately acted on, approved, or cleared the submissions. A consequence of this approach is that the statistics shown for a particular year may change from one report to the next. This is because as time passes, FDA completes work on more and more submissions within a cohort. As more submissions are completed, the statistics for that year of receipt must be adjusted to reflect the new completions. Until all submissions in a cohort are completed, only a preliminary performance assessment can be provided for that cohort.

Original PMAs/PMRs and Panel-track PMA Supplements

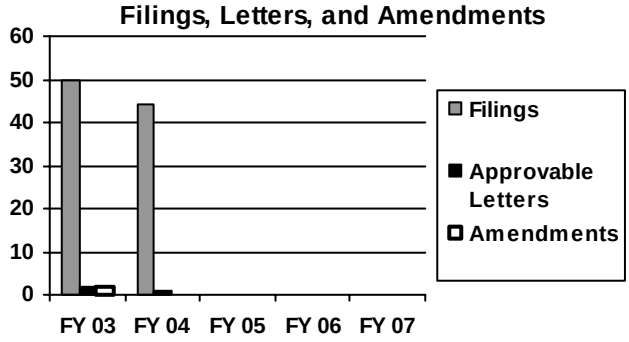
Goal – Act on an amendment containing a complete response to an "approvable" letter

The MDUFMA goal for actions on amendments containing a complete response to an "approvable" letter applies to original PMAs, Premarket Reports (PMRs), and Panel-track PMA Supplements. MDUFMA requires FDA to review and act on 90 percent of amendments containing a complete response to an "approvable" letter within 30 days. The table below summarizes the review time goal for such amendments.

Amendment Type	Review Time Goal	Performance Goal FY 2003 – FY 2007 Submissions
Original PMAs/PMRs	30 days	90% on time
Panel-track PMA Supplements		

Workload

The total number of PMAs/PMRs and panel-track PMA supplements filed in FY 2004 dropped when compared to FY 2003. Only two amendments to approvable letters have been submitted; both were for submissions filed in FY 2003.



Filings, Letters, and Amendments					
Type	FY 03	FY 04	FY 05	FY 06	FY 07
Total Filings *(Original PMAs and PMRs/ Panel-track PMA Supplements)*	**50** *(43/7)*	**44** *(39/5)*	--	--	--
Approvable Letters	**2**	**1**	--	--	--
Amendments	**2**	**0**	--	--	--

Original PMAs/PMRs and Panel-track PMA Supplements

Performance

FY 2003 Submissions

FDA filed 43 PMAs and PMRs, seven panel-track PMA supplements and issued two "approvable" letters as of September 30, 2004 for FY 2003 submissions. FDA received a complete response amendment to these two "approvable" letters and responded to one within the 30 days allowed under this performance goal. With submissions still pending, it is too early to make a final determination for FY 2003.

FY 2003 Submissions					
Submission Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**MDUFMA Performance Goal**	**Percent on Time**
Amendment containing a complete response to an "approvable" letter	30 days	2	1	90%	50%

FY 2004 Submissions

As of September 30, 2004, FDA had not issued any "approvable" letters for applications in this cohort, and had not had an opportunity to receive any amendments containing a complete response to the FDA "approvable" letter. With submissions still pending, it is too early to make a final determination for FY 2004.

FY 2004 Submissions					
Submission Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**MDUFMA Performance Goal**	**Percent on Time**
Amendment containing a complete response to an "approvable" letter	30 days	0	0	90%	--

Expedited Original PMAs

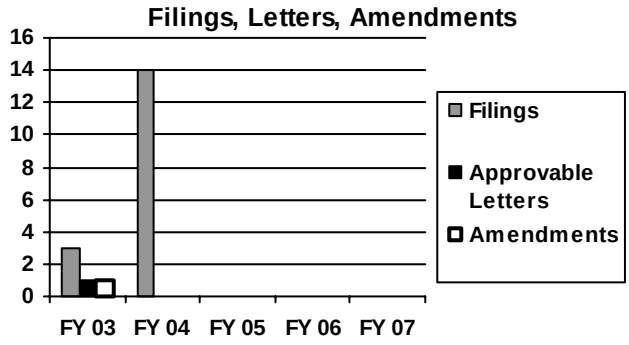
Goal – Act on an amendment containing a complete response to an "approvable" letter

The MDUFMA goal for actions on amendments containing a complete response to an "approvable" letter applies to expedited original PMAs and is identical to the goal for original PMAs/PMRs and Panel-track PMA Supplements. MDUFMA requires FDA to review and act on 90 percent of amendments containing a complete response to an "approvable" letter within 30 days. The table below summarizes the review time goal for such amendments.

Amendment Type	Review Time Goal	Performance Goal FY 2003 – FY 2007 Submissions
Expedited Original PMAs	30 days	90% on time

Workload

The number of expedited PMAs filed increased substantially in FY 2004. Only one amendment in response to an "approvable" letter has been submitted and was for a submission filed in FY 2003.



Filings, Letters, and Amendments					
Type	FY 03	FY 04	FY 05	FY 06	FY 07
Expedited Original PMAs	3	14	--	--	--
Approvable Letters	1	0	--	--	--
Amendments	1	0	--	--	--

Expedited Original PMAs

Performance

FY 2003 Submissions

FDA filed three expedited PMAs and issued one "approvable" letter as of September 30, 2004 for FY 2003 submissions. FDA received a complete response amendment to this "approvable" letter and responded within the 30 days allowed under this performance goal; FDA ultimately approved that expedited PMA. With submissions still pending, it is too early to make a final determination for FY 2003.

FY 2003 Submissions					
Submission Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**MDUFMA Performance Goal**	**Percent on Time**
Amendment containing a complete response to an "approvable" letter	30 days	1	1	90%	100%

FY 2004 Submissions

As of September 30, 2004, FDA had not issued an "approvable" letter for any expedited PMA in this cohort, and had not received any amendments containing a complete response to the FDA "approvable" letter. FDA approved one expedited PMA in this cohort without first issuing an "approvable" letter. With submissions still pending, it is too early to make a final determination for FY 2004.

FY 2004 Submissions					
Submission Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**MDUFMA Performance Goal**	**Percent on Time**
Amendment containing a complete response to an "approvable" letter	30 days	0	0	90%	--

Additional MDUFMA Performance Commitments

This section reports on the additional commitments outlined in FDA's Commitment Letter. A detailed description of the commitments, performance targets, and definitions of terms can be found in Appendix A (section I, paragraphs I - P).

Maintenance of Current Performance

FDA's FY 2004 performance in review areas that do not have specific MDUFMA performance goals is comparable to FY 2003 and FY 2002 performance (performance prior to enactment of MDUFMA). The following table provides examples of sustained performance by product submissions.

CDRH Performance Indicators	FY 02	FY 03	FY 04
HDEs — Filing to first action (average FDA days)	53	39	44
HDEs — Elapsed time to approval (average FDA days)	60	44	57
IDEs — FDA review time (average FDA days)	28	27	28
IDEs — Percent of decisions made within 30 days	99%	100%	100%
IDE Amendments — FDA review time (average FDA days)	18	19	18
IDE Amendments — Percent of decisions made within 30 days	100%	100%	100%
IDE Supplements — FDA review time (average FDA days)	20	19	19
IDE Supplements — Percent of decisions made within 30 days	100%	100%	100%
CBER Performance Indicators	FY 02	FY 03	FY 04
BLA Supplements — CBE/CBE-30 – Percent of decisions made within 6 months	99%	97%	100%
PMA Supplements – CBE — Percent of decisions made within 180 days	100%	100%	100%
PMA Supplements – 135-day — Percent of decisions made within 135 days	*NR*	100%	100%
PMA Supplements – CBE-30 — Percent of decisions made within 30 days	67%	100%	100%
KEY: HDEs–Humanitarian Device Exemptions; IDEs–Investigational Device Exemptions; BLA-Biologic License Application; PMA-Premarket Application; CBE-Changes Being Effected; NR-None Received			

Some reported measures may change over time, as additional actions are taken on open applications.

Meetings with Regulated Industry

FDA continues to encourage meetings as a particularly effective way to ensure that both FDA and applicants understand the clinical, scientific, and regulatory issues associated with new technologies. Pre-IDE and pre-PMA meetings have proven to be particularly beneficial and are used routinely by industry. During FY 2004, FDA reviewed more than 300 pre-IDE submissions and held more than 100 pre-IDE meetings. The more formal types of meetings (agreement meetings, determination meetings, 100-day meetings) are not used as frequently by premarket applicants. FDA is working to ensure that the need to meet MDUFMA's many quantitative performance goals (which require a great deal of focused attention) does not result in delays in scheduling and holding meetings with applicants.

Reviewer Training and Hiring

FDA is working to strengthen and expand its capacity to conduct efficient and timely reviews to ensure the safety and effectiveness of new medical devices. The Agency has made a good start towards hiring the additional staff that will be needed to improve the device review processes and meet the performance goals established for FDA under MDUFMA.

FDA was not able to hire new staff to implement MDUFMA until after FDA received its appropriation for FY 2003 on February 20, 2003. Prior to that time, FDA began implementing MDUFMA with existing staff. FDA's implementation of MDUFMA accelerated beginning with the second half of FY 2003, as FDA was able to begin hiring and training new staff. During FY 2004, FDA hired medical officers, consumer safety officers, chemists, microbiologists, biomedical engineers, statisticians, scientists, project managers, IT specialists, and other specialized staff. FDA also expanded the use of contractors and outside experts, providing additional flexibility to meet nonrecurring workloads, to augment FDA resources in highly specialized areas, and to achieve particular tasks at a lower cost than would otherwise be possible.

- **Resources Applied to MDUFMA Activities.** During FY 2003, CDRH increased the resources applied to the process for the review of device applications by 6 FTEs over FY 2002 while also constructing new program infrastructure for the review of device applications.[8] During FY 2004, CDRH applied 54 more FTEs than FY 2003 (60 FTEs over FY 2002). CDRH projects that during FY 2005, 92 FTEs more than FY 2004 will be applied; this will mean CDRH will have increased the resources available to the process for the review of device applications by 152 FTEs since FY 2002.

CDRH Resources (FTEs) Applied to the Process for the Review of Device Applications				
Process	**FY 02**	**FY 03**	**FY 04**	**(Projected) FY 05**
Premarket Review	529	534	575	660
Related Activities	146	147	160	167
Total	**675**	**681**	**735**	**827**
Increase Compared to FY 02	--	6	60	152

For FY 2003, CBER received 11 FTEs for MDUFMA implementation.[9] The process for the review of device applications required 58 FTEs. For FY 2004, CBER received an additional 9 FTEs for MDUFMA implementation, and estimated that the device review program required 67 FTEs. CBER has used MDUFMA resources to add medical and technical expertise in a variety of fields, such as infectious diseases, blood establishment computer software, blood collecting and processing devices, and blood banking reagents and equipment.

[8] The "process for the review of device applications" is defined by section 737(5) of the FD&C Act.

[9] CBER's regulatory responsibilities and workload demands are such that its personnel who are involved in medical device reviews are also expected to be involved with other workloads, such as biologics reviews. The 11 FTEs authorized for MDUFMA workloads will be spread over many new hires, each to work partly on device activities and partly on other workloads. Consequently, it is not appropriate to describe these new hires as being within a particular category of employee.

- **Hiring of New Personnel.** CDRH has hired almost all of its new personnel on term appointments. This approach is consistent with stakeholders' expectations that FDA will hire staff to meet critical needs as they arise and to meet those needs with a flexible approach that can be modified as the Agency's needs change. This approach also reflects the uncertainty surrounding MDUFMA funding.[10]

Hiring (category)/Number of Positions (not FTEs)		
Position	**FY 03**	**FY 04**
Scientist	26	19
Engineer	16	12
Statistician	6	9
Consumer Safety Officer	9	3
Medical Officer / Nurse	4	5
Project Manager	6	2
Program Support	7	5
Attorney	1	0
Total Hiring	**75**	**55**

- **Medical Device Fellowship Program.** CDRH has established a Medical Device Fellowship program as a way to identify, recruit, and employ highly-specialized expertise. Participation in the program can be tailored to the interests of both CDRH and participants, making it a very flexible tool for meeting changing Center needs. As of October 1, 2004, 64 fellows were participating in the program.

Medical Device Fellowship Participation as of October 1, 2004	
Category	**Participants**
Engineers	42
Physicians	15
Scientists	5
Physicists	2
Total Participants	**64**

- **Training.** CDRH and CBER have begun to train staff on the new guidance and procedures required to effectively implement MDUFMA, and have engaged in numerous training activities. Both Centers have also developed plans that will significantly increase clinical and technical training in the coming years.

Modular PMA Review Program

FDA issued initial guidance on modular PMA reviews in its guidance document, *Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products*, on February 25, 2003. This guidance explained that the

[10] FDA's FY 2003 appropriation was delayed until February 2003, and the appropriations enacted for FY 2003 and FY 2004 were below the minimum levels required by section 738(g)(1) of the FD&C Act (this provision was added by section 102 of MDUFMA).

fee for a modular PMA submission was due upon submission of the *first module* (not just the "shell" that described the overall plan for the modular submission).

On November 23, 2003, FDA provided a more comprehensive guidance document, *Premarket Approval Application Modular Review*; this guidance provided industry and FDA staff with information regarding the modular review program and outlined the procedures for submitting and reviewing a modular PMA. As FDA gains more experience with the modular PMA process, it will consult with stakeholders to develop performance goals for this program.

Note: FDA determined that it will not assess a MDUFMA review fee for any modular PMA submission whose first module was received prior to the statutory effective date of MDUFMA (October 1, 2002). FDA will receive additional modules for these PMAs for years to come, but will not receive any review fees for this considerable workload.

Bundling Policy

After consulting with stakeholders, FDA determined that bundling is appropriate under certain circumstances. On February 25, 2003, FDA issued initial guidance describing general bundling principles in its guidance document, *Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products*. This guidance explained that bundling may involve multiple devices or multiple indications for use in a single submission. On November 26, 2003, FDA provided a more comprehensive guidance document, *Bundling Multiple Devices or Multiple Indications in a Single Submission*. This guidance was intended to help industry and FDA staff understand when bundling may be appropriate, when separate submissions should be considered, and provided numerous examples illustrating these bundling principles for both 510(k) and PMA applications. Interest in bundling has increased since MDUFMA was enacted, and FDA is now receiving considerable numbers of bundled submissions.

Electronic Review of Applications

FDA published *Guidance for Industry. Providing Regulatory Submissions to CBER in Electronic Format - Investigational New Drug Applications (INDs)* (March 26, 2002), which applies to investigational studies of devices, such as blood screening test kits, leading to a BLA. CBER contributed to guidance documents on electronic submissions in general, and received a number of electronic submissions for biologic (non-device) reviews. To date, CBER has not received electronic submissions of any medical device applications.

CBER continues to make a significant outreach effort to inform regulated industry of the process for electronic submissions. In particular, during all sponsor meetings, CBER informs applicants and potential applicants of the ability to submit electronic documents. In addition, CBER is making provisions for secure e-mail when not associated with an original electronic application.

CDRH is working with applicants to expand the use of electronic submissions, focusing first on increasing the use of electronic copies of applications. During FY 2004, CDRH received 48 submissions for PMAs, IDEs, 510(k)s, and other applications from 16 different sponsors entirely in electronic form. Instructions for making electronic submissions to CDRH are available at www.fda.gov/cdrh/elecsub.html. CDRH initiated a "Turbo 510(k)" pilot in the Office of In-Vitro Diagnostics Device Evaluation and Safety, providing an electronic template for submission and review of *in vitro* diagnostic device 510(k)s.

Preapproval Inspections

During FY 2003, FDA began a comprehensive examination of factors affecting the timeliness and efficiency of the preapproval inspection process to determine how the process can be improved and what resources would be required to make those improvements. During FY 2004, FDA continued to examine alternatives to improve the timeliness and efficiency of the process, and began to develop guidance to: 1) help industry better understand the preapproval inspection process, so they will be better prepared for their inspections; and 2) explain how the Centers will work with applicants, the Office of Regulatory Affairs, and with its field inspectors to improve the timeliness of preapproval inspections; this will include clearly-defined milestones in the preapproval inspection process to help ensure more timely scheduling and completion of inspections.

FDA expects to issue this guidance during FY 2005. The Agency expects the guidance, combined with associated process improvements, will help FDA meet both this goal and the PMA goals.

Next Steps to Implement MDUFMA Successfully

FDA faces a number of critical implementation steps in meeting MDUFMA's performance goals which grow progressively more challenging each year through FY 2007. These include building critical infrastructure, hiring and training additional staff, making greater use of external expertise, and reengineering our review processes to provide for more timely and efficient device reviews. Additionally, FDA will work with the Administration and Congress to ensure continued success of the device user fee program.

FDA needs to address the following implementation challenges to achieve the improvements promised by MDUFMA.

- Develop data systems that ensure each device review subject to a user fee is linked to the correct user fee payment and systems to measure FDA's review performance against the many goals established under MDUFMA. This will require new internal systems, as well as systems to link very different databases in FDA's Office of the Commissioner, CBER, and CDRH.

- Move forward with electronic application submission and review systems and processes.
- Hire and train additional FDA scientists, engineers, statisticians, and other staff to: better distribute review workloads, expand the opportunity for meetings and other interaction with applicants, expand and update guidance documents used by applicants to prepare high-quality applications, and undertake the many additional efforts that will be required to meet or exceed MDUFMA's performance goals.
- Make greater use of external expertise to ensure timely action on medical device reviews that involve novel new technologies or unusual efforts.
- Ensure timely pre-approval inspections, both within the United States and abroad.
- Develop new processes for modular PMA reviews, and to work with stakeholders to develop meaningful performance goals for these reviews.
- Ensure that device reviews are completed in as few cycles as possible, thereby speeding the introduction of important new medical technologies and providing greater predictability in the reviews.

Appendix A: November 14, 2002, Commitment Letter from DHHS Secretary Thompson to Congress

THE SECRETARY OF HEALTH AND HUMAN SERVICES

Washington, DC, November 14, 2002

Hon. EDWARD KENNEDY
U.S. Senate
Washington, DC

DEAR MR. CHAIRMAN:

As you are aware, the Medical Device User Fee and Modernization Act of 2002 was signed by the President on October 26, 2002. Under Title I, the additional revenues generated from fees paid by the medical device industry will be used to expedite the medical device review process, in accordance with performance goals that were developed by the Food and Drug Administration (FDA) in consultation with the industry.

FDA has worked with various stakeholders, including representatives from consumer, patient, and health provider groups, and the medical device industry to develop legislation and goals that would enhance the success of the device review program. Title I of the Medical Device User Fee and Modernization Act of 2002 reflects the fee mechanisms and other improvements developed in these discussions. The performance goals referenced in Section 101 are specified in the enclosure to this letter, entitled "Performance Goals and Procedures." I believe they represent a realistic projection of what FDA can accomplish with industry cooperation and the additional resources identified in the bill.

This letter and the enclosed goals document pertain only to title I (Fees Related to Medical Devices) of Public Law 107-250, Medical Device User Fee and Modernization Act of 2002. OMB has advised that there is no objection to the presentation of these views from the standpoint of the Administration's program. We appreciate the support of you and your staffs, the assistance of other Members of the Committee, and that of the Appropriations Committees, in the authorization of this vital program.

Sincerely,

TOMMY G. THOMPSON

MDUFMA PERFORMANCE GOALS AND PROCEDURES

The performance goals and procedures of the FDA Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER), as agreed to under the medical device user fee program in the Medical Device User Fee and Modernization Act of 2002, are summarized as follows:

I. REVIEW PERFORMANCE GOALS — FISCAL YEAR 2003 THROUGH 2007

All references to "days" mean "FDA days."

A. ORIGINAL PREMARKET APPROVAL (PMA), PANEL-TRACK PMA SUPPLEMENT, AND PREMARKET REPORT SUBMISSIONS

1. The following cycle goals apply to: 75% of submission received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

(a) First action major deficiency letters will issue within 150 days.

(b) All other first action letters (approval, approvable, approvable pending good manufacturing practices (GMP) inspection, not approvable, or denial) will issue within 180 days.

(c) Second or later action major deficiency letters will issue within 120 days.

(d) Amendments containing a complete response to major deficiency or not approvable letters will be acted on within 180 days.

2. Decision Goals:

(a) 80% of submissions received in fiscal year 2006 will have an FDA decision in 320 days.

(b) 90% of submissions received in fiscal year 2007 will have an FDA decision in 320 days.

3. Subject to the following paragraph, 50% of submissions received in fiscal year 2007 will have an FDA decision in 180 days.

This goal will be re-evaluated following the end of fiscal year 2005. FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in fiscal year 2007. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the Committee on Health, Education, Labor and pensions of the Senate and to the Energy and Commerce Committee, Subcommittee on Health of the House of Representatives stating that the goal will not be implemented and the rationale for its removal.

4. 90% of amendments containing a complete response to an approvable letter received in fiscal years 2003 through 2007 will be acted on within 30 days.

B. EXPEDITED ORIGINAL PMA SUBMISSIONS

1. The following goals apply to PMA submissions where:

(a) FDA has granted the application expedited status;

(b) The applicant has requested and attended a pre-filing review meeting with FDA;

(c) The applicant's manufacturing facilities are prepared for inspection upon submission of the application; and

(d) The application is substantively complete, as defined at the pre-filing review meeting.

2. The following cycle goals apply to: 70% of submissions received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

(a) First action major deficiency letters will issue within 120 days.

(b) All other first action letters (approval, approvable, approvable pending GMP inspection, not approvable, or denial) will issue within 170 days.

(c) Second or later action major deficiency letters will issue within 100 days.

(d) Amendments containing a complete response to major deficiency or not approvable letters will be acted on within 170 days.

3. Decision Goals:

(a) 70% of submissions received in fiscal year 2005 will have an FDA decision in 300 days.

(b) 80% of submissions received in fiscal year 2006 will have an FDA decision in 300 days.

(c) 90% of submissions received in fiscal year 2007 will have an FDA decision in 300 days.

4. 90% of amendments containing a complete response to an approvable letter received in fiscal years 2003 through 2007 will be acted on within 30 days.

C. 180-DAY PMA SUPPLEMENT SUBMISSIONS

1. The following goals apply to: 80% of submissions in fiscal year 2005; 85% of submissions in fiscal year 2006; 90% of submissions in fiscal year 2007.

(a) First action not approvable letters will issue within 120 days.

(b) All other first action letters (approval, approvable, approvable pending GMP inspection, or denial) will issue within 180 days.[11]

(c) Amendments containing a complete response to a not approvable letter will be acted on within 160 days.

2. Decision Goals:

(a) 80% of submissions received in fiscal year 2005 will have an FDA decision in 180 days.

(b) 80% of submissions received in fiscal year 2006 will have an FDA decision in 180 days.

(c) 90% of submissions received in fiscal year 2007 will have an FDA decision in 180 days.

3. Current performance for real-time review PMA supplement submissions will be maintained.

[11] This text was edited from the original version. "Not approvable" was taken out of the list of "All other first action letters." Because "Not approvable" letter is already captured under the "First Action" goal of 120 days, it should not be repeated under the "All other first actions" goal of 180 days.

D. 510(k) SUBMISSIONS

1. The following goals apply to: 70% of submissions received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

(a) First action additional information letters will issue within 75 days.

(b) Subsequent action letters will issue within 60 days.

2. Decision Goals:

(a) 75% of submissions received in fiscal years 2005 and 2006 will have an FDA decision in 90 days.

3. Subject to the following paragraph, 80% of submissions received in fiscal year 2007 will have an FDA decision in 90 days.

This goal will be re-evaluated following the end of fiscal year 2005. FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in fiscal year 2007. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the Committee on Health, Education, Labor and Pensions of the Senate and to the Energy and Commerce Committee, Subcommittee on Health of the House of Representatives stating that the goal will not be implemented and the rationale for its removal, and that the goal for fiscal year 2006 will be implemented for fiscal year 2007.

E. ORIGINAL BIOLOGICS LICENSING APPLICATIONS (BLAs)

The following goals apply to: 75% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

1. Review and act on standard original BLA submissions within 10 months of receipt.

2. Review and act on priority original BLA submissions within 6 months of receipt.

F. BLA EFFICACY SUPPLEMENTS

The following goals apply to: 75% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

1. Review and act on standard BLA efficacy supplement submissions within 10 months of receipt.

2. Review and act on priority BLA efficacy supplement submissions within 6 months of receipt.

G. ORIGINAL BLA AND BLA EFFICACY SUPPLEMENT RESUBMISSIONS

The following goals apply to: 75% of submissions received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

1. Review and act on Class 1 original BLA and BLA efficacy supplement resubmissions within 2 months of receipt.

2. Review and act on Class 2 original BLA and BLA efficacy supplement resubmissions within 6 months of receipt.

H. BLA MANUFACTURING SUPPLEMENTS REQUIRING PRIOR APPROVAL

The following goal applies to: 75% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

Review and act on BLA manufacturing supplements requiring prior approval within 4 months of receipt.

I. ADDITIONAL EFFORTS RELATED TO PERFORMANCE GOALS

The Agency and the regulated industry agree that the use of both informal and formal meetings (e.g., determination and agreement meetings, informal pre-investigational device exemption (IDE) meetings, pre-PMA meetings, pre-PMA filing meetings) by both parties is critical to ensure high application quality such that the above performance goals can be achieved.

J. MAINTENANCE OF CURRENT PERFORMANCE

It is the intent of the Agency that in review areas where specific performance goals have not been identified, current performance will be maintained.

K. APPLICATION OF USER FEE REVENUES

The Agency intends to apply significant user fee revenues to support reviewer training and hiring and/or outside contracting to achieve the identified performance goals in a responsible and efficient manner.

L. MODULAR PMA REVIEW PROGRAM

The Agency intends to issue guidance regarding the implementation of new section 515(c)(3) of the Federal Food, Drug, and Cosmetic Act. It is the intent of the Agency that once this program is implemented, the Agency will work with its stakeholders to develop appropriate performance goals for this program. Until such time, the Agency intends to review and close complete modules that are submitted well in advance of the PMA submission as expeditiously as possible.

M. "FOLLOW-ON" LICENSED DEVICES

The Center for Biologics Evaluation and Research will, if feasible, identify a category of "follow-on" licensed devices and collect information to determine whether alternative performance goals for such a category are appropriate.

N. BUNDLING POLICY

The Agency will, in consultation with its stakeholders, consider the issue of bundling for products with multiple related submissions. After such consultation, the Agency will either issue guidance on bundling or publish a notice explaining why it has determined that bundling is inappropriate.

O. ELECTRONIC REVIEW OF APPLICATIONS

The Agency will continue its efforts toward development of electronic receipt and review of applications, as expeditiously as possible, acknowledging that insufficient funding is included in the user fee program for this effort.

P. PREAPPROVAL INSPECTIONS

The Agency will plan to improve the scheduling and timeliness of preapproval inspections. The Agency will monitor the progress of these efforts and provide such information in the annual performance report.

II. ANNUAL STAKEHOLDER MEETING

Beginning in fiscal year 2004, FDA will hold annual public meetings to review and evaluate the implementation of this program in consultation with its stakeholders.

III. DEFINITIONS AND EXPLANATION OF TERMS

A. For original PMA submissions, Panel-Track PMA supplement submissions, expedited original PMA submissions, 180-day supplement submissions, and premarket report submissions, issuance of one of the following letters is considered to be an FDA decision:

1. approval
2. approvable
3. approvable pending GMP inspection
4. not approvable
5. denial

B. For 510(k) submissions, issuance of one of the following letters is considered to be an FDA decision:

1. substantially equivalent (SE)
2. not substantially equivalent (NSE)

C. Submission of an unsolicited major amendment to an original PMA submission, Panel-Track PMA supplement submission, expedited original PMA submission, 180-day supplement submission, or premarket report submission extends the FDA decision goal date by the number of days equal to 75% of the difference between the filing date and the date of receipt of the amendment. The submission of the unsolicited major amendment is also considered an action that satisfies the first or later action goal, as applicable.

D. For BLA (original, efficacy supplement, or manufacturing supplement) submissions, the term "review and act on" is understood to mean the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

E. For original BLA and BLA efficacy supplement resubmissions:

1. Class 1 resubmitted applications are applications resubmitted after a complete response letter that include the following items only (or combinations of these items):

(a) Final printed labeling
(b) Draft labeling
(c) Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)
(d) Stability updates to support provisional or final dating periods
(e) Commitments to perform Phase 4 studies, including proposals for such studies
(f) Assay validation data
(g) Final release testing on the last 1-2 lots used to support approval
(h) A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the Class 1 category)
(i) Other minor clarifying information (determined by the Agency as fitting the Class 1 category)
(j) Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

2. Class 2 resubmissions are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

Appendix B: Measuring Performance Under MDUFMA

Different types of performance goals require different types of performance measures. FDA measures its success in meeting MDUFMA's goals and commitments in two ways: using *quantitative* measures and using *descriptive* measures, depending on how the objective for a particular performance goal is described in FDA's commitment letter. If the commitment letter provides an objective standard against which to measure our progress, we use quantitative measures. If the commitment letter does not provide an objective standard, FDA uses descriptive measures.

Quantitative Measures

Quantitative progress is measured and described primarily through standard, quantifiable statistics (for example, number of submissions, mean performance, median performance, percent meeting a review time standard). Each quantitative goal has the following characteristics:

- a clear definition of the submissions to which the goal applies (e.g., expedited PMAs),
- a clear definition of the action FDA is to take (e.g., issue a first action major deficiency letter),
- an objective review time standard (i.e., the number of days or months within which FDA is expected to take action),
- a quantifiable measure of performance (i.e., the minimum percent of submissions for which FDA is expected to meet the review time standard), and
- a specific time frame within which the goal applies (i.e., the fiscal year for which FDA performance will be evaluated).

MDUFMA's review performance goal progress is measured using quantitative methods.[12] Most of these goals use measures of success that become significantly more challenging over time.[13] This approach recognizes that FDA must first hire and train new staff and rebuild review program infrastructures before it will be possible to make substantial progress in improving overall review performance, while providing interim goals that allow periodic evaluation of FDA's progress towards the ultimate goals of the program.

[12] These are defined in section I, paragraphs A through H, of FDA's Commitment Letter. A tabular summary of all of MDUFMA's objective performance goals is provided in Attachment C.

[13] For example, Section I, paragraph B, goal 3(a) of FDA's Commitment Letter sets the following goal for Expedited PMAs: "70% of submissions received in fiscal year 2005 will have an FDA decision in 300 days." This is a quantitative goal because it applies to a defined category of applications (expedited PMAs), involves a defined type of action (an FDA decision), sets an objective review time standard (300 days), has a quantifiable measure of successful performance (70% of submissions), and applies within a specific time frame (FY 2005).

Example: An example of where a performance goal is evaluated through quantitative measures is an Expedited PMA, received during FY 2005, when FDA's first action is a "major deficiency" letter. FDA will take that action (issue the letter) within 150 days of receipt of the Expedited PMA [(FDA Commitment Letter, section I, paragraph B, Item 2(a)].

Descriptive Measures

When quantitative measure cannot be used to evaluate FDA's progress in implementing a performance goal, the Agency uses descriptive measures to assess its performance. The Agency reports its progress in narrative accounts that outline the specific actions FDA has taken, the results are attributed to those actions.

MDUFMA's commitments use descriptive measures to assess performance.[14] For descriptive measures, progress is reported through narrative accounts outlining specific actions taken, in addition to any results attributed to those actions. Descriptive measures:

- do not involve an objective review time standard
- do not have a quantifiable measure of successful performance, and
- do not specify the time frame within which it must be completed.

FDA regards all of MDUFMA's descriptive performance commitments to be in effect beginning with FY 2003 and will report progress towards achieving these commitments each year in the annual performance report.

Example: An example of where a performance goal is evaluated using descriptive measures is when FDA issues guidance on modular reviews under section 515(c)(3), and works with stakeholders to develop appropriate performance goals for the modular review program [(FDA Commitment Letter, section I, paragraph L].

Receipt Cohorts

FDA measures its performance against applications in a *receipt cohort*. This methodology records performance on a submission in the statistics for the year it was *received*, regardless of when FDA ultimately acted on, approved, or cleared that submission. A consequence of this approach is that the statistics shown for a particular year may change from one report to the next. This is because, as time passes, FDA completes all work on more and more submissions. As more submissions are completed, the statistics for that year of receipt must be adjusted to reflect the new completions.

[14] Defined in section I, paragraphs I through P, of FDA's Commitment Letter.

Eligible Submissions Under MDUFMA

The performance goals of MDUFMA do not apply to device submissions received prior to FY 2003. Although FDA will work diligently to improve review performance for *all* applications, regardless of when they were received, submissions received prior to FY 2003 will not be reflected in the *performance statistics* used to evaluate FDA's progress towards meeting MDUFMA's goals. Submissions received since the start of FY 2003 (October 1, 2002) are subject to MDUFMA's performance goals, and will be reflected in FDA's performance statistics.

Appendix C: Summary of MDUFMA's Quantitative Goals

This table summarizes all of MDUFMA's quantifiable review performance goals (section I, goals A through H, in DHHS Secretary Thompson's November 14, 2002, Commitment Letter).

Activity	Review Time	Performance Level (by FY) (— indicates no quantitative goal)				
		2003	2004	2005	2006	2007
PMAs, Panel-Track Supplements, Premarket Reports						
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	320 days	—	—	—	80%	90%
• FDA decision – median performance	180 days	—	—	—	—	50%[15]
• First action – "major deficiency" letter	150 days	—	—	75%	80%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	—	—	75%	80%	90%
• Second or later action – "major deficiency" letter	120 days	—	—	75%	80%	90%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	180 days	—	—	75%	80%	90%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	90%	90%	90%	90%
Expedited PMAs These goals apply when FDA has granted expedited status; the applicant has attended a pre-filing meeting; manufacturing facilities are ready for inspection; and the PMA is substantively complete as defined at the pre-filing meeting.						
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	300 days	—	—	70%	80%	90%
• First action – "major deficiency" letter	120 days	—	—	70%	80%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	170 days	—	—	70%	80%	90%
• Second or later action – "major deficiency" letter	100 days	—	—	70%	80%	90%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	—	—	70%	80%	90%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	90%	90%	90%	90%

[15] These goals will be re-evaluated following the end of FY 2005. FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in FY 2007. If FDA determines that a goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the Committee on Health, Education, Labor and Pensions of the Senate and to the Energy and Commerce Committee, Subcommittee on Health of the House of Representatives stating that the goal will not be implemented and the rationale for its removal.

Activity	Review Time	Performance Level (by FY) (— indicates no quantitative goal)				
		2003	2004	2005	2006	2007
180-day PMA Supplements						
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	—	—	80%	80%	90%
• First action – "not approvable" letter	120 days	—	—	80%	85%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, or denial)	180 days	—	—	80%	85%	90%
• Action on an amendment containing a complete response to a "not approvable" letter	160 days	—	—	80%	85%	90%
510(k)s						
• FDA decision (SE/NSE)	90 days	—	—	75%	75%	80%[†]
• First action – "additional information" letter	75 days	—	—	70%	80%	90%
• Second or later action	60 days	—	—	70%	80%	90%
Biologics Licensing Applications - BLAs						
• Review and act on standard original BLAs (issue "complete action" letter)	10.0 months	—	—	—	75%	90%
• Review and act on priority original BLA submissions (issue "complete action" letter)	6.0 months	—	—	—	75%	90%
BLA Supplements						
• Review and act on standard BLA efficacy supplements (issue "complete action" letter)	10.0 months	—	—	—	75%	90%
• Review and act on priority BLA efficacy supplements (issue "complete action" letter)	6.0 months	—	—	—	75%	90%
• Review and act on BLA manufacturing supplements that require prior approval (issue "complete action" letter)	4.0 months	—	—	—	75%	90%
BLA Resubmissions, BLA Supplement Resubmissions						
• Review and act on a Class 1 resubmission to an original BLA or BLA efficacy supplement (issue "complete action" letter)	2.0 months	—	—	75%	80%	90%
• Review and act on a Class 2 resubmission to an original BLA or BLA efficacy supplement (issue "complete action" letter)	6.0 months	—	—	75%	80%	90%

Note: Definitions for the terms used here are provided in Section III of the FDA's Commitment Letter.

Appendix D: Glossary

Class – Each generic type of device is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device: Class I - General Controls, Class II - General Controls and Special Controls, and Class III - General Controls and Premarket Approval.

Humanitarian Device Exemption (HDE) – An application that is similar to a premarket application (PMA), but exempt from the effectiveness requirements of a PMA. An approved HDE authorizes marketing of a Humanitarian Use Device (HUD).

Investigational Device Exemption (IDE) – An IDE allows an investigational device to be used in a clinical study.

Modular Review Program for Premarket Applications (PMAs) – A mechanism by which an applicant may submit preclinical data and manufacturing information for review while still collecting, compiling, and analyzing the clinical data. A modular PMA is a compilation of sections or "modules" submitted at different times that together become a complete application.

Panel-track PMA Supplement – A supplemental application to an approved PMA or premarket report that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness.

Premarket Application (PMA) – An application providing scientific and medical data to show that a Class III medical device is reasonably safe and effective for its intended use.

Premarket Notification [510(k)] – An application that demonstrates that the medical device to be marketed is substantially equivalent (SE) to a legally-marketed device that was or is currently on the U.S. market.

- **Substantially Equivalent (SE)** – A device is substantially equivalent to a legally marketed device.
- **Not Substantially Equivalent (NSE)** – A device is not substantially equivalent to the already legally marketed device.

Premarket Report (PMR) – A type of premarket application for a reprocessed single-use device.

Product Development Protocol (PDP) – An alternative to a PMA, based on early consultation between the sponsor and the FDA, that leads to a device development and testing plan acceptable to both parties. It minimizes the risk that the sponsor will pursue the development of a device that FDA will not approve.

This report was prepared by FDA's Office of Planning in collaboration with the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health. For information on obtaining additional copies contact:

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